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1 **Effect of time on biomechanical measures during exercise on the**
2 **Functional Re-adaptive Exercise Device**

3
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25 **Effect of time on biomechanics during exercise on the Functional** 26 **Re-adaptive Exercise Device**

28 **Abstract**

29 Mechanistic studies of the Functional Re-adaptive Exercise Device (FRED) have
30 shown it automatically recruits Lumbar Multifidus (LM) and Transversus Abdominis
31 (TrA) – two deep-spinal muscles that are atrophied and show altered motor control
32 in low back pain (LBP). No studies have investigated the time required to
33 familiarise to FRED exercise, which is required to inform future FRED based
34 clinical trial protocols. This study therefore determined the effect of time, during
35 FRED exercise, on biomechanical outcome measures, to establish the familiarisation
36 period, and assess for loss of technique throughout a ten minute trial. A cohort
37 comparison study of 148 participants, 70 experiencing low back pain, had
38 lumbopelvic kinematics, exercise frequency and movement variability measured
39 during a 10 minute trial. Magnitude-based inference was used to assess for
40 familiarisation, using plots of variation over time with familiarised reference ranges.
41 The no pain group took 170 seconds, and the back pain group took 150 seconds, to
42 familiarise. A familiarisation period of at least 170 seconds (2.8 minutes) is
43 recommended. This justifies, and provides a familiarisation time for use of the
44 FRED as a motor control intervention.

46 **Keywords:** Motor control, spinal rehabilitation, Lumbar Multifidus, Transversus
47 Abdominis

48 **Manuscript metrics:** Abstract words: 181. Main text (Introduction through the
49 discussion) words: 3415. References: 30. Tables: 2. Figures: 1.

50 **Introduction**

51 Low back pain (LBP) costs over £1billion per year (NICE, 2009) in addition
52 to psychosocial challenges, creating a need for low cost and effective treatments.

53 While LBP is multifactorial(Panjabi, 2006), spinal robustness at an inter-segmental
54 level (Panjabi, 1992a, 1992b) and changes in spinal mechanics (Panjabi, 2006) are
55 commonly reported elements. An adequate level of spinal robustness is required to
56 ensure static and dynamic stability of the spine with robustness referring to both
57 stability and how the spine, muscles and motor control system cope with
58 disturbances such as a perturbation (Reeves, Narendra, & Cholewicki, 2008). The
59 Lumbar Multifidus muscle (LM) provides segmental stiffness (Kiefer, Shirazi-Adl,
60 & Parnianpur, 1998; Panjabi, 1992a) and controls lumbar lordosis(Claus, Hides,
61 Moseley, & Hodges, 2009) while the Transversus Abdominis muscle (TrA) provides
62 segmental robustness by increasing intra-abdominal pressure (J. Hides, Stanton,
63 Mendis, & Sexton, 2011b; Hodges, 2004). Dysfunction and atrophy of both muscles
64 has been linked with a lack of spinal robustness and therefore LBP (J. Hides,
65 Lambrecht, Stanton, & Damann, 2015; J. Hides, et al., 2011b; Hodges and Moseley,
66 2003; Saunders, Coppieters, & Hodges, 2004; Wallwork, Stanton, Freke, & Hides,
67 2009). It is often difficult for individuals to voluntarily recruit these muscles,
68 especially LM(Van, Hides, & Richardson, 2006), which is a challenge for
69 rehabilitation.

70 Recently, the Functional Re-adaptive Exercise Device (FRED), that aims to
71 target recruitment of the LM and TrA muscles, has undergone mechanistic
72 investigations to assess its potential as an intervention for LBP and determine future
73 clinical trial protocol parameters (Caplan, Gibbon, Hibbs, & Debuse, 2014; Debuse,
74 Birch, Gibson, & Caplan, 2013; Gibbon, Debuse, & Caplan, 2013). Exercise on the

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75 FRED involves a combination of weight-bearing, an unstable base of support (at the
76 feet) and an upright posture with a robust lumbo-pelvic region during functional
77 lower-limb cyclical motion at a slow target speed. The FRED is similar to an
78 elliptical trainer but with no resistance and a requirement to perform the movement
79 with minimal variability in movement speed. A more detailed description of the
80 movement on FRED and determination of target exercise speed, with images, is
81 available elsewhere (2017c). Recent studies of FRED exercise shows it
82 automatically recruits both LM and TrA (Debusse, et al., 2013; Winnard, et al.,
83 2017c) through a tonic contraction (Caplan, et al., 2014) with no conscious input, as
84 well increasing spinal robustness (Gibbon, et al., 2013) and placing the spine into a
85 more optimal position for LM and TrA activity compared to walking, which is a
86 similar upright functional exercise (Winnard, D., Wilkinson, Tahmosybayat, & N.,
87 2017b) . These studies have justified clinical trials of FRED as an intervention for
88 LBP.

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89 To date, FRED studies have included exercise familiarisation periods of two
90 to three minutes (Debusse, et al., 2013), or five minutes (Caplan, et al., 2014; Gibbon,
91 et al., 2013; Winnard, D., et al., 2017b; Winnard, et al., 2017c). These
92 familiarisation periods, however, have not been determined objectively. As a final
93 stage of the mechanistic studies, before a clinical trial, it was necessary to determine
94 the time required to familiarise to FRED exercise in terms of pelvic and spinal
95 kinematics, exercise frequency and movement variability. The same familiarisation
96 time could also be used clinically, should the device prove useful from clinical trials,
97 without clinicians having to rely on arbitrary or trial and error derived familiarisation
98 periods. The aim of this study was therefore determined the effect of time, during

99 FRED exercise, on biomechanical outcome measures, to establish the familiarisation
100 period, and assess for loss of technique throughout a ten minute trial.
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103 **Methods**

104 The study protocol was approved by the Northumbria University ethics
105 committee. Participants provided written informed consent before participating.
106 One hundred and forty eight participants were recruited from the general public, with
107 a mean (\pm SD) age, height and mass of 36.7 (\pm 9.0) years, 1.72 (\pm 0.09) m, and 77.8
108 (\pm 17.5) kg, respectively. The study was conducted fully open to the general public
109 at a local science museum in Newcastle-Upon-Tyne as part of a “Meet the Scientist”
110 interactive exhibit and the general public visiting the museum over a four week
111 period were able to choose to take part in the study. Exclusion criteria included
112 being aged under 18 or over 55 years, having a history of neuromusculoskeletal
113 problems or injuries resulting in scoliosis or inability to exercise safely on the
114 FRED, being pregnant, having heart disease and having had abdominal or spinal
115 surgery in the last three years. In addition, four participants’ kinematic data and
116 seven participants’ FRED data were excluded due to technical errors with data not
117 having been recorded for them. All participants were required to pass the Physical
118 Activity Readiness Questionnaire prior to testing. Using the same method as earlier
119 FRED studies (Winnard, D., et al., 2017b), all participants were divided into two
120 groups for comparison, those with and those without back pain. This was done by
121 asking participants “how much back pain have you had in the past 4 weeks?”
122 (modified question 7 of the Short Form-36 (SF-36), standard, US version 2
123 (QualityMetric, 2000)). Participants indicated their pain score, ranging from 1 (no
124 pain) to 6 (very severe pain). Low-back pain scores of 2 or more designated
125 participants as having back pain for analysis. There were 78 participants who
126 reported no back pain, and 70 who reported at least very mild back pain.

127

128 **Protocol**

129 Six hundred seconds of kinematic, exercise frequency and foot-movement
130 variability data were simultaneously collected during FRED exercise from the
131 moment participants began exercising on the device. Participants were first time
132 FRED users and did not undertake a pre-exercise familiarisation period. Explanation
133 was given of the visual feedback which the device provides to help users maintain a
134 target frequency of 0.42 Hz that produces a slow movement consistent across all
135 participants and FRED studies. The target frequency was designed to force users to
136 exercise in a slow and smooth movement, that is expected to be more useful than
137 fast or jerky movements, for promoting core stability and spinal robustness (details
138 published in previous paper (Winnard, et al., 2017c)). The foot movement amplitude
139 can be adjusted on the FRED and for this study was set to the smallest amplitude
140 (0.2 m) for all participants. The smallest amplitude setting was selected as it
141 considered to be the easiest setting for the first time users and is in line with our
142 other studies (Winnard, et al., 2017c; Winnard, Debuse, Wilkinson, Tahmosybayat,
143 & Caplan, 2017b).

144

145 **Outcome measures**

146 Lumbopelvic kinematics were assessed by measuring sagittal plane joint
147 angles at L5/S1, L3/L4, T12/L1 and T8/T9 and pelvic tilt. These measures are
148 relevant to LM and TrA training, as they provide an estimate of full lumbar lordosis,
149 lower thoracic kyphosis and sagittal plane pelvic tilt and were the same as those
150 measured in a previous study (2017b). Current clinical LM and TrA training aims to
151 promote and maintain lumbar lordosis within the lumbar spine (O'Sullivan et al.,
152 2006; Roussouly, Gollogly, Berthonnaud, & Dimnet, 2005) as LM controls the

153 lumbar lordosis (Claus, et al., 2009). Kinematics were assessed using a wearable-
154 motion-capture system (MVN, XSens, Enschede). The system consists of a series of
155 motion tracking devices placed at key locations within a wearable suit that was
156 placed over a single layer of participant's clothing, who wore t-shirt and trousers, in
157 line with published guidelines (Roetenberg, Luinge, & Slycke, 2013) and our
158 previous study methods (Winnard, D., et al., 2017b). Seventeen sensors containing a
159 3D gyroscope, 3D accelerometer and a magnetometer, were secured to the hands,
160 forearms, upper arms, head, scapulae, pelvis, upper legs, lower legs and feet. An
161 image of the exact tracker locations is available elsewhere (2017b). Participants
162 were required to remove footwear throughout the trials to prevent any confounding
163 effect of footwear design. Full body kinematic data were collected at 80 Hz, using
164 the default full body model and Kinematic Coupling Algorithm (KiC) fusion engine
165 setting. Local magnetic interference can cause drift over prolonged use of this
166 system, so the magnetometer input was disabled to minimise drift errors. For
167 modelling the spinal segments, data is taken from the sacrum, sternum, scapulae and
168 head trackers. The spine is divided into segments with joints estimating movements
169 at L5S1, L3L4, L1T12 and T9T8. The movements of these joints were estimated by
170 the software using interpolation between the trackers. This is the default setup
171 recommended by the XSens user manual, which states these segment definitions
172 match International Society of Biomechanics recommendations (XSens, 2012). Data
173 from the trackers is used to displace the default spinal model. The displacement
174 movement is divided across several segment joints based on a stiffness assigned to
175 each segment within the software.
176

177 The Xsens system was reported as having up to two degrees of error for
178 dynamic accuracy in roll, pitch and heading linked to centre of mass and pelvic tilt
179 data, and an angular resolution for joint angle estimation of 0.05 degrees (Lebel,
180 Boissy, Hamel, & Duval, 2015). The system has been validated against the gold
181 standard VICON 3D system for measuring kinematic data (Roetenberg, et al., 2013)
182 and shown to have good correlation with optical motion capture systems for
183 estimated 3D kinematics at the L5S1 level (Faber, Chang, Kingma, Dennerlein, &
184 van Dieen, 2016).

185
186 Exercise frequency and foot movement variability were assessed using a
187 rotary encoder built into the FRED (RP6010, ifm Electronic GmbH, Essen,
188 Germany). Frequency was calculated as the number of crank cycles per second
189 (Hz). Movement variability was quantified as the difference (%) between the
190 instantaneous-angular velocity of movement and the mean-angular velocity over the
191 previous second. This was recorded as a negative change if the live velocity was
192 decreasing and positive if it was increasing. Movement variability data were made
193 absolute for analysis, meaning a high movement variability value indicated uneven
194 movement while a movement variability of zero represented perfectly even
195 movement (i.e. constant angular velocity of the feet). The frequency and movement
196 variability data were recorded at 5 Hz on a second PC, running custom software.
197 This sampling rate was the fastest the FRED hardware and software was able to
198 record. The frequency and movement variability data was collected over the same
199 time period as the Xsens data. The data were imported into Microsoft Excel 2010
200 for analysis.

201

202 **Data analysis:**

203 Familiarisation time was defined as the time at which participants first achieved
204 correct technique after movement initiation. Correct FRED exercise technique
205 requires upright posture and a relatively stable lumbopelvic region, during slow and
206 controlled cyclical-functional movements of the lower limbs (Debusse, et al., 2013).
207 Poor exercise technique may therefore be defined as variation beyond the amount
208 measured during a period of familiarised exercise.

209
210 The mean and standard error of the mean (SEM), across each participant was
211 calculated for every data point for both groups, as used in previous biomechanical
212 familiarisation studies (Moore and Dixon, 2014). The mean \pm SEM range was
213 plotted as a function of time for flexion angle at L5/S1, L4/L3, L1/T12, T8/T9,
214 anterior pelvic tilt, exercise frequency and movement variability. To enable clear
215 analysis, without losing the overall pattern, several filtering options were assessed.
216 The smallest moving average which reduced noise sufficiently to allow clear
217 analysis to be made was selected. A moving average filter was therefore selected for
218 each variable with a time window of 2.5 seconds before and after each data point.

219
220 All data appeared to have plateaued, indicating familiarisation, by 2.5
221 minutes and remained stable until at least 4.5 minutes, showing no loss of technique
222 occurred within this period. Therefore the mean between 2.5 and 4.5 minutes was
223 used as a familiarised reference. The familiarised reference mean \pm the mean SEM
224 of each measure between 2.5 and 4.5 minutes was plotted as a familiarisation
225 reference range based on the likely range of the true mean. Familiarisation was
226 estimated to be the point (to the nearest 5 second interval) at which the mean \pm SEM

227 across all participants fully entered into the familiarisation reference range for each
228 variable. Any variables that crossed over the familiarised region, before the 2.5
229 minute point and continued to fluctuate while still overlapping the familiarised
230 range and before reaching an obvious plateau were not considered familiarised until
231 fluctuations decreased and the plateau was reached.

232
233 Magnitude based inference (MBI) was used to determine if the mean
234 difference before and after the familiarisation point was at least as large as the
235 familiarised reference SEM. Magnitude based inference has recently been proved a
236 trustworthy alternative to traditional significance testing and outperforms in sample
237 size, error rates and publication bias (W. G. Hopkins and Batterham, 2016). For all
238 estimated points, the mean difference, 90% confidence intervals and probabilities
239 (%) that the true values of the statistic were mechanistically positive, trivial or
240 negative based on the smallest worthwhile change (familiarisation reference SEM)
241 were reported and qualitatively defined by the following scale recommended by
242 Hopkins, et al. (2008) as <0.5% is “*most unlikely*”, <5% is “*very unlikely*”, <25% is
243 “*unlikely*”, 25-75% is “*possible*”, >75% is “*likely*”, >95% is “*very likely*”, and
244 >99.5% is “*most likely*”. All inferences which were at least likely (>75%) were
245 highlighted using bold text in the results. Full raw data sets are available from the
246 authors on request.

247

248 **Results**

249 Table 1 presents the pain and no pain group demographics. The group
250 demographics and any differences found with MBI are, therefore, presented taking
251 these exclusions into account. Any differences between the groups were *trivial*.

252

253 Figure 1 illustrates the mean \pm SEM for L5/S1 kinematics as an example
254 variable, throughout the 600 second trials, compared to the familiarised reference
255 ranges, in both the pain and no pain groups. All other familiarisation figures can be
256 requested as supplementary data from the authors. The reference familiarisation
257 ranges are marked with horizontal dashed lines on the plots and any estimated
258 familiarisation points by vertical dotted lines. Table 2 presents the raw change in
259 mean and 90% confidence limits of each measure, before and after the estimated
260 familiarisation and loss of technique points, and MBI.

261

262 All flexion angles were familiarised by 40 seconds, in the no pain group and
263 45 seconds in the pain group, and flexion decreased during the familiarisation period
264 in both groups. Table 2 shows it was *likely* that flexion angles were positive in both
265 groups before the estimated familiarisation point, compared to afterwards.

266

267 Pelvic tilt appeared familiarised by 105 seconds in the no pain group and 110
268 seconds in the pain group, decreasing during the familiarisation period in the no pain
269 group and increasing in the pain group. However, Table 2 shows that it was *unlikely*
270 that anterior pelvic tilt was positive before the familiarisation point in the no pain
271 group and *unlikely* negative before familiarisation in the pain group, compared to
272 afterwards. The mean pelvic tilt data always overlapped the familiarised range and
273 so familiarisation was estimated to be the point of plateau within the range.

274

275 Exercise frequency was familiarised by 70 seconds in the no pain group and
276 15 seconds in the pain group. Frequency decreased during the familiarisation period

277 in the no pain group and increased in the pain group. Table 2 shows it was *likely* that
278 frequency was positive before the estimated 70 second familiarisation point in the no
279 pain group, compared to afterwards. However, it was only *possible* that frequency
280 was negative before the 15 second estimated familiarisation point in the pain group,
281 compared to afterwards. The mean pelvic frequency always overlaps the
282 familiarised range and so familiarisation was estimated to be the point of plateau
283 within the range.

285 Movement variability was familiarised by 130 seconds of exercise in the no
286 pain group and 155 seconds in the pain group. Movement variability decreased
287 during the familiarisation period in both the no pain and pain groups. Table 2 shows
288 that before the estimated 130 and 150 familiarisation points, in the no pain and pain
289 groups respectively, movement variability was *most likely* positive, compared to
290 afterwards.

292 Discussion

293 The main finding of this study was that it took up to 170 seconds to
294 familiarise to FRED exercise in the no pain group and up to 150 seconds in the pain
295 group. Spinal positioning was the first element to familiarise in both groups. Spinal
296 positioning started in a more flexed position and gradually extended at all measured
297 angles during familiarisation. This agrees with a previous study of 130 participants
298 that showed FRED promotes extension in the lower portion of the spine compared to
299 walking (Winnard, D., et al., 2017b). Exercise frequency increased in the no pain
300 group and decreased in the pain group, while movement variability gradually
301 decreased in both groups, throughout familiarisation. No *likely* mechanistic change

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302 in pelvic tilt orientation occurred throughout the 600 second trials. Previous research
303 (Gibbon, et al., 2013) and the reference data both showed that FRED exercise places
304 the pelvis into increased anterior tilt compared to walking, and so it appears from
305 this study that the shift in pelvic tilt occurs immediately on initiating exercise.
306

307 It is known that the LM and TrA muscles are active in a more tonic pattern
308 during FRED exercise than walking(Caplan, et al., 2014), and more active than at
309 rest(Debusse, et al., 2013). It is also known that LM has a role in spinal positioning,
310 with increasing activity when the lumbar spine extends into a lordotic curve below
311 the thoracolumbar junction (Claus, et al., 2009; O'Sullivan, et al., 2006; Roussouly,
312 et al., 2005). As spinal posture is the first element to familiarise it is reasonable to
313 imply that the LM muscle is likely to be active by 40 seconds of exercise in those
314 without, and by 45 seconds in those with, back pain. The remaining familiarisation
315 time then appears to be taken up by attempting to reach an even paced global
316 movement pattern at the target frequency. In the no pain group, movement
317 variability familiarised by 130 seconds followed by exercise frequency at 170
318 seconds. This suggests that device users focus first on achieving an even movement
319 followed by reaching the correct frequency. However, those with back pain had no
320 *likely* frequency familiarisation time suggesting they were able to reach the target
321 frequency from initiating movement. The target frequency provided by the
322 feedback was 0.42 Hz as per the rationale explained in Winnard et al.(2017c) and it
323 is felt that users are familiarised once they are able to exercise close to this frequency
324 with low movement variability. The familiarised frequency ranges were found to be
325 0.48 ± 0.01 Hz for the no-LBP group and 0.50 ± 0.01 Hz for the LBP group. The no-
326 LBP group were, therefore, able to exercise closer to the target frequency, whereas

the LBP group had a frequency that was 0.12 Hz faster. This finding might suggest that those with no back LBP had better motor control. If so, this could be an indication of the FRED being a potentially useful intervention to improve motor control but this needs testing in clinical trials.

331

Additionally, despite the much quicker frequency familiarisation time which led to a faster overall familiarisation time, the LBP group took 20 seconds longer to develop familiarised movement variability. As people with LBP often have reduced motor control of deep lumbopelvic muscles such as LM (J. A. Hides, Stokes, Jull, & Cooper, 1994; Hodges and Moseley, 2003; Panjabi, 2006) it is unsurprising that they took more time to develop the motor control required to refine the movement, and showed reduced ability to reach the target exercise frequency. This finding therefore adds to the justification of a clinical trial of the FRED as an intervention for challenging and training lumbopelvic motor control in LBP patients to test this possibility.

342

Only six participants indicated experiencing severe or very severe pain. Therefore, the back pain results are mostly representative of populations with very mild to moderate back pain and should be treated with caution in populations with severe or worse pain. The back pain group does not necessarily represent a group that would all benefit from spinal motor control rehabilitation.

348

For first time users of the FRED, it took 170 seconds to familiarise to the exercise in terms of pelvic and spinal kinematics, exercise frequency and movement variability, while overall familiarisation occurred 20 seconds earlier in participants

with back pain as they moved at the slow target frequency from the start of exercise. Those with back pain took 20 seconds longer to achieve a consistent movement pattern, probably due to reduced motor control, and demonstrated less ability to modulate exercise frequency, suggesting the intervention might be useful as a motor control intervention. Therefore, it is recommended that future FRED activities include a familiarisation period of at least 170 seconds to allow correct lumbopelvic positioning and control of the movement to be reached.

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Figure captions

Figure 1. Mean L5/S1 flexion angle across all participants throughout the 600 second trial in; a. the no pain group and b. the pain group. Familiarisation range shown on plots between dashed lines is no pain group: 2.7 ± 0.3 , pain group: 3.4 ± 0.3 (degrees).

Figure

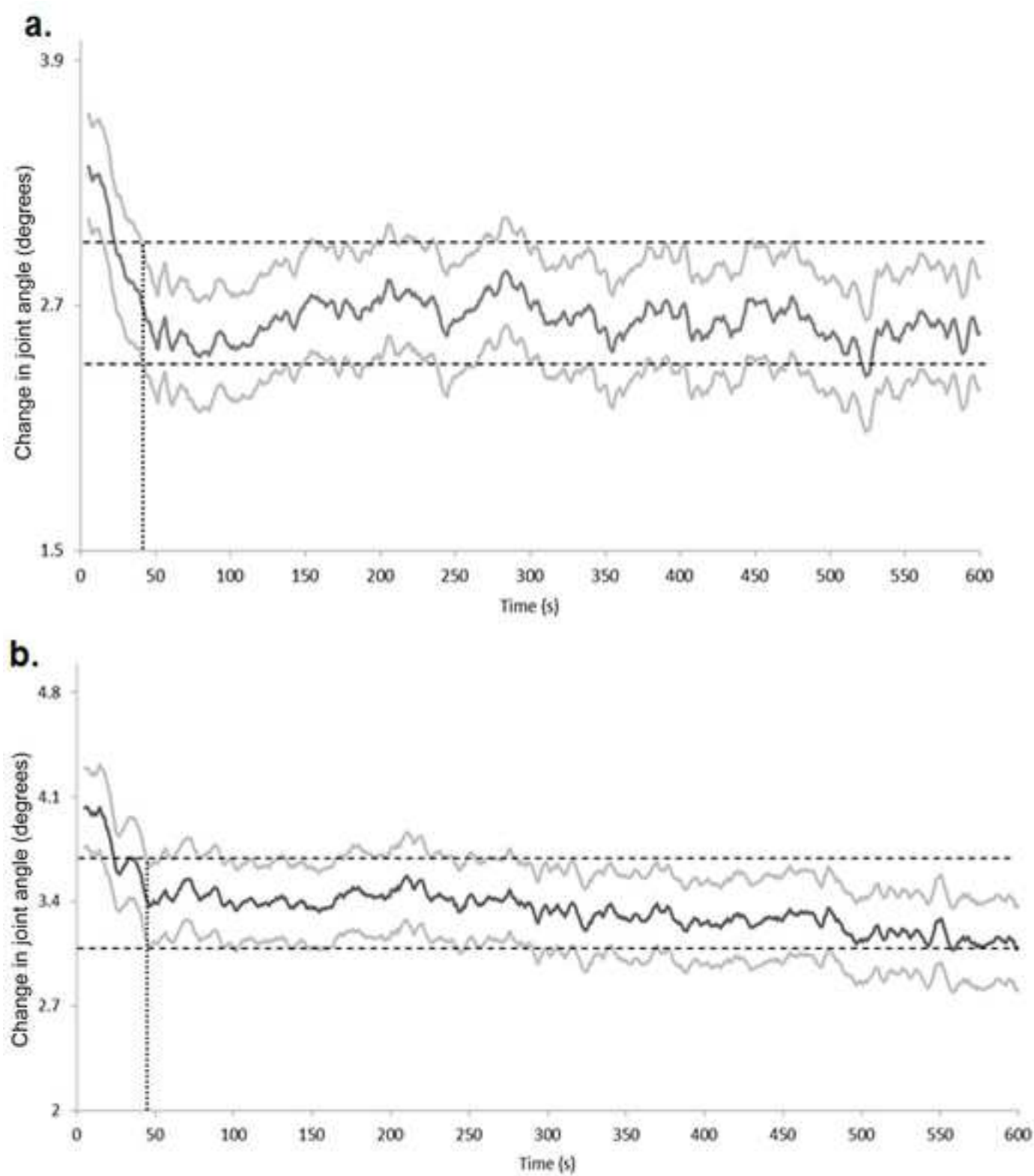


Table 1. Group demographics and chance that any group differences are trivial using an inference threshold of 0.6 standardised mean change.

	n	Gender (M/F)	Age (years)	Mass (kg)	Height (m)	BMI
Kinematic data						
All participants	144	73/71	36.5	77.8	1.72	26.3
Back pain	67	33/34	37.6	80.3	1.72	27.1
No pain	77	40/37	35.7	75.6	1.72	25.6
Chance (%) that difference between pain and no pain groups is trivial			100	97	100	100
FRED data						
All participants	141	71/70	36.8	78.4	1.72	26.3
Back pain	67	33/34	37.6	81.1	1.72	27.2
No pain	74	38/36	36.1	75.9	1.72	25.6
Chance (%) that difference between pain and no pain groups is trivial			100	94	100	98

Table 2. Differences in L5/S1, L3/L4, T12/S1 and T8/T9 flexion angles, pelvic tilt, exercise frequency and movement variability pre and post familiarisation point.

Group	Comparison time point	Raw change	90% confidence limits		Mechanistic inference
L5/S1 flexion angle. Inference threshold: 0.3 degrees no pain and pain group					
No pain	40 s	0.4	0.6	0.2	Likely +ve
Pain	45 s	0.4	0.6	0.2	Likely +ve
L3/L4 flexion angle. Inference threshold: 0.1 degrees no pain and pain group					
No pain	40 s	0.2	0.3	0.1	Likely +ve
Pain	45 s	0.2	0.3	0.1	Likely +ve
T12/L1 flexion angle. Inference threshold: 0.1 degrees no pain and pain group					
No pain	40 s	0.2	0.3	0.1	Likely +ve
Pain	45 s	0.2	0.3	0.1	Likely +ve
T8/T9 flexion angle. Inference threshold: 0.1 degrees no pain and pain group					
No pain	40 s	0.1	0.2	0.0	Likely +ve
Pain	45 s	0.2	0.2	0.1	Likely +ve
Anterior pelvic tilt. Inference threshold: 0.1 degrees no pain and pain group					
No pain	105 s	0.4	0.4	0.0	Unlikely +ve
Pain	110 s	-0.4	0.1	-0.9	Unlikely -ve
Exercise frequency. Inference threshold: 0.014 Hz no pain and pain group					
No pain	170 s	-2.4	-1.5	-3.3	Very likely -ve
Pain	15 s	1.7	4.0	-0.7	Possibly +ve
Movement variability. Inference threshold: 1.5% no pain and 1.6% pain group					
No pain	130 s	4.2	4.8	3.6	Most likely +ve
Pain	155 s	3.2	3.6	2.7	Most likely +ve

Threshold for inferences using mean SEM between 2.5 and 4.5 minutes is indicated in table. All raw change and confidence limits are in degrees.